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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,508	10/12/2000	Scott A. Ruddell	DI-5654	9098

29200 7590 01/24/2005

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/689,508	RUDDELL ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *36, 37, 74-94* is/are withdrawn from consideration.

5)☒ Claim(s) *29,31-35,44-48,50-58,60,61,99-101,103-108,110-113 and 115* is/are allowed.

6)☒ Claim(s) *1-8,10-16,18,20-28,38-43,62-66,68-71,73 and 95-97* is/are rejected.

7)☒ Claim(s) *17 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-8,10-29,31-35,38-58,60-66,68-71,73,95-97,99,101,103-108,110-113 and 115.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28, 38-43, 62-66, 68-71, 73 and 95-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 (and its dependent claims 26-28), claim 38 (and its dependent claims 39-43), claim 62 (and its dependent claims 63-66 and 68), claim 69 (and its dependent claims 70, 71, 73), claim 95 (and its dependent claims 96-97) are vague for the following reason. Claim 25, lines 7-8, claim 38, line 8, claim 62, lines 12-13, claim 69, lines 11-12, and claim 95, line 4, all recite the limitation "a patient/tube connection location", but it is not clear as to which portion of the catheter the patient/tube connection is located. (For example, it is not clear as to the structural relationship between the patient/tube connection and the external portion of implantable portion.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-8, 10-16, 18 and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Clayman et al., 6,656,146.

As to claim 1, Clayman discloses a tube (510, figure 5A)) having an implantable portion (512 and *distal* portion of "upper segment", figure 5A, column 6, line 61) extending from an external patient portion (i.e., portion of tube proximal to implantable portion, including the *proximal* portion of "upper segment" column 6, line 61), the implantable portion having a curved segment (512, column 6, lines 32-34) and a substantially straight section (distal portion of "upper segment", column 6, lines 60-61) between the external patient portion and a distal end of the implantable portion; a first lumen (main lumen, column 3, line 37) extending through the tube from a first lumen port in the external patient portion to a first lumen port (openings, see figure 5A and also column 5, lines 4-9) in the curved segment of the implantable portion; and a second lumen (bladder lumen, column 3, line 38) extending through the tube from a second lumen port (openings, see figure 5A and also column 5, lines 4-9) in the external patient portion to a second lumen port in the implantable portion, the second lumen port (i.e., an opening along the tubular segment that is spaced away from curved segment 512, column 5, lines 9-10) in the implantable portion being spaced away from the curved segment.

As to claim 3, the first lumen port in the curved segment comprises a plurality of openings (column 5, lines 4-5, and see figure 5A) at an outer radial surface of the curved segment.

As to claims 4, 7 and 10, the plurality of openings are substantially round holes, see Figure 5A.

As to claims 5, 8 and 11, the plurality of openings are considered slots, see Figure 5A.

As to claim 6, the implantable portion (512) has a coiled shape at the distal end, see Figure 5A.

As to claim 12, the tube is a single tube having a septum between the first and second lumens, (figure 5A, and column 3, lines 35-37.)

As to claim 13, the first lumen port in the curved segment is capable of being a patient inflow port, (column 3, lines 4-5, and figure 5A.)

As to claim 14, the second lumen port in the implantable portion is a patient outflow port, (column 3, lines 4-5.)

As to claim 15, the first lumen terminates prior to the distal end of the implantable portion, (column 3, lines 35-38.) (Clayman teaches that "at least the bladder end region of the tubular segment may include two lumens", thereby indicating that the bladder end region need not have two lumens.)

As to claim 16, Clayman discloses a **connection section** (i.e., *proximal* portion of "upper segment", figure 5A, column 6, line 61) having an inflow port (openings, see figure 5A and also column 5, lines 4-9; the port is capable of permitting inflow) to a

patient inflow lumen, and an outflow port (any of the other openings, see figure 5A and also column 5, lines 4-9; the port is capable of permitting outflow) to a patient outflow lumen; a **patient inflow section** (distal portion of "upper segment", figure 5A, column 6, line 61) extending from the connection section and having a patient inflow opening (openings, see figure 5A and also column 5, lines 4-9) to the patient inflow lumen; a **separation section** (i.e., proximal portion of 512) extending from the patient inflow section; and a **patient outflow section** (i.e., distal portion of 512) extending from the separation section and having a patient outflow opening (openings, see figure 5A and also column 5, lines 4-9) to the patient outflow lumen wherein the patient inflow section is located closer to a position on the connection section that is suitable for attachment to a patient's body than to the patient outflow section.

As to claim 18, the patient outflow section (distal portion of 512) is coiled (figure 5A).

As to claim 20, the patient inflow section is considered an uppermost portion of an implantable portion of the catheter and the patient outflow section is considered a lowermost portion of the implantable portion of the catheter.

As to claim 21, the connection section, patient inflow section, separation section, and patient outflow section further comprise a flexible tube having an internal septum between the patient inflow and outflow lumens (column 3, lines 36-39.)

As to claim 22, the connection section and patient inflow section are both portions of (512), the separation section and patient outflow sections are both portions of "upper segment" described in column 6, line 61.

As to claims 23 and 40, the patient inflow opening to the patient inflow lumen is in a direction away from the patient outflow opening to the patient outflow lumen.

As to claims 24, 41 and 42, the catheter comprises a single tube having the patient inflow and outflow lumens, and wherein the tube transitions from having both the patient inflow and outflow lumens to having only the patient outflow lumen at a location between the patient inflow section and a distal catheter end (column 3, lines 35-38; Clayman teaches that "at least the bladder end region of the tubular segment may include two lumens", thereby indicating that the bladder end region need not have two lumens.)

2. Claims 25-28, 38-43, 62-66, 68-71, 73 and 95-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Sommercorn et al., 4,543,087

As to claims 25-28, Sommercorn discloses a tube (10) having lumens of differing lengths (see figure 1), the tube having an external patient portion (distal portion of 10) and implantable portion (proximal portion of 10), the first lumen extending from a first fluid opening (40) to a second fluid opening (38), the second lumen extending from a third fluid opening (32) to a fourth fluid opening (34), the first and third fluid openings being in an external patient portion, the second and fourth fluid openings being in an implantable portion of the catheter and spaced apart from each other such that a second fluid opening (38) is positioned closer to a patient/tube connection location (distal end of 10, starting where external patient portion ends) than the second fluid opening is positioned with respect to the forth fluid opening (34), and wherein the

implantable portion is non-linear in shaped (when it is bent for example, since Applicant has not claimed that the non-linear shape is pre-formed.)

As to claims 38, 62, 73 and 95, Sommercorn discloses a dialysate supply and removal system (column 1, line 6); a catheter (10) connected to the system, the catheter having implantable first and second lumens of differing lengths (see figure 1), the first lumen in a side-by-side arrangement relative to the second lumen (see figure 1), a first lumen outflow (38) positioned closer to a patient/catheter connection location (distal end of 10) on the catheter than the first lumen outflow is positioned with respect to a second lumen inflow (34), the catheter so positioned and arranged when in use in a peritoneal cavity that fluid flows out of the first lumen in an upper area of the peritoneal cavity and into the second lumen in a lower area of the peritoneal cavity (Column 2, lines 25-27.)

As to claims 39, 40, 63, 64, 65, 68 and 70, the system is automated, and conveys fluid through both lumens (column 1, line 6, column 2, lines 25-27.)

As to claims 41-43, 66, 69, 71, 96 and 97, the catheter is a dual lumen catheter and has different lengths (see figure 1.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clayman et al., 6,656,146, in view of Moncrief et al., 5,057,075.

Clayman discloses the invention substantially as claimed, see above. Clayman discloses a ureteral stentfor assisting movement of urine along a patient's ureter and into the patient's bladder. However, Clayman does not disclose an implant cuff.

Moncrief et al. discloses a catheter having a cuff (24) that is amenable to in-growth of living tissue, see column 2, lines 19-25,wherein the catheter is to be implanted and used for peritoneal dialysis or for providing access to a particular mechanism of the body such as a circulation system or an internal, artificial or transplanted organ (column 2, lines 13-18.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an implant cuff taught by Moncrief on the Clayman device to allow in-growth of living tissue onto the cuff which is desirable for implanted catheters such as the Clayman catheter, as taught by Moncrief.

Allowable Subject Matter

4. Claims 17 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 29, 31-35, 44-48, 50-58, 60, 61, 99-101, 103-108, 110-113 and 115 are allowed.

Response to Arguments

Applicant's arguments with respect to the amended claims 25-28, 38-43, 62-66, 68-71, 73 and 95-97 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the unamended claims have been considered but are not persuasive. In response to applicant's argument on page 22 that Clayman does not teach an external patient portion, which is discussed in the specification as being located outside of the patient's body when implanted, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the external patient portion in Clayman as described in the above rejections are capable of being located outside a patient.

Likewise, in response to Applicant's argument on page 23 that the lumen in the Clayman device is meant to house and protect suture material as opposed to transporting fluid, the Clayman lumen is capable of performing this intended use and thus meets the claims.

Applicant also argues on pages 23 through 24 that if the holes at the end of the stent of Clayman are taken to be the patient outflow opening of the patient outflow section, then there is no structure in Clayman corresponding to the patient inflow section which is spaced apart from the patient outflow section by a separation section. Examiner points to the rejection of claim 16 above, which states that the outflow port is any of the openings in figure 5A and the patient outflow section is proximal portion of (512), and the patient inflow section is distal portion of "upper segment" (see fig. 5A, col. 6, line 61.)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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1/14/05